

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

FUNDA et al

Atty. Ref.: 4662-121; Confirmation No. 2120

Appl. No. 10/564,635

TC/A.U. 1619

Filed: January 13, 2006

Examiner: Greene

For: POWDEROUS FORMULATIONS OF FAT-SOLUBLE ACTIVE INGREDIENTS

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**EVIDENTIARY DECLARATION UNDER 37 CFR §1.132**

I, Elger Manuel Funda, hereby declare as follows:

1. That I am a joint inventor of the subject application, am a citizen of Germany and my address is as stated in our Declaration under Rule 63 (37 CFR §1.63) of record in the subject application.
2. That I am employed by DSM Nutritional Products Ltd. and have assigned my rights in the subject application to DSM IP Assets B.V.
3. That attached hereto is my curriculum vitae.
4. That the following experiments were conducted by me or under my supervision:

The following example, which falls under the amended claims, has been made:

72 g of sodium caseinate and 18 g of rice protein hydrolysate (molecular weight distribution <2000 D = min. 95 %) were added to 300 ml of water and 10.8 g of glycerol. The mixture was warmed to 60 °C until dissolution occurred. To this solution, 18.1 g of sugar fructose were added and the pH of the solution was adjusted to 6.5 ± 0.2. Thereafter, 50 g of vitamin A acetate (2.1x

$10^6$  IE vitamin A /g stabilized with Ethoxyquin) were emulsified into the matrix solution whereupon the mixture was stirred for 45 minutes at 60 °C. The inner phase of the emulsion then exhibited a mean particle size of about 410 nm. The emulsion was then diluted with ca. 55 ml of water and about 300 g of the emulsion was sprayed in a spraying pan in a bed of Ca-silicate at about 5 °C by means of a rotating spraying nozzle. The so-obtained beadlets were separated from excess Ca-silicate by sieving and dried. There were obtained ca. 85 g of dry powder having a vitamin A content of ca. 730'000 IEA/g.

50 g of the so-obtained dry powder were cross-linked by thermically treating the powder at 125 °C in a rotating dryer for 25 minutes. The so-obtained product had a vitamin A content of ca. 660'000 IE per g and was insoluble in hot water.

The inventiveness of the embodiments of the amended set of claims of step of the present US patent application can be seen in the examples of the application and the additional example. Examples 1 and 2 of the present US patent application do not fall under the scope of the amended set of claims anymore. They now serve as comparative examples. Examples 3 and the Example as described above (Example 4) are falling under the scope of the amended set of claims.

Accordingly, the applicant tried – as shown in the following table – to extract the most important data pertaining to the unexpected success in increasing the content of fat-soluble active ingredients.

Example number	vitamin A content <u>before cross-linking</u>	vitamin A content <u>after cross-linking</u>	yield
1 (comparative)	750'000 IE/g	450'000 IE/g	60.0 %
2 (comparative)	750'000 IE/g	500'000 IE/g	66.6 %
3 (according to invention)	735'000 IE/g	605'000 IE/g	<b>82.3 %</b>
4 (according to invention)	730'000 IE/g	660'000 IE/g	<b>90.4 %</b>

We believe that the results summarized in the table clearly show the surprising superiority of the present invention over the prior art.

5. We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: March 23<sup>rd</sup> 2011



Elger Manuel Funda

**EXHIBIT 1**  
***Curriculum vitae***

**Name:** Elger Manuel Funda  
**Birthplace:** Stuttgart (Germany)  
**Date of birth:** 5<sup>th</sup> November 1966  
**Nationality:** German

**Degrees**

Abitur, Ludwigsburg (Germany), 1985  
Diploma in Chemistry, University of Stuttgart (Germany), 1994  
PhD in Chemistry, University of Stuttgart (Germany), 1998

**Professional experience**

1998-2001 Scientist at Fraunhofer Institute for Process Engineering and Packaging, Freising (Germany)  
2001- Formulation Scientist at DSM Nutritional Products / Roche Vitamins, Basel/Kaiseraugst (Switzerland)

**Major research interests**

Formulation and encapsulation of active ingredients for food-, feed- and pharma-applications.  
Formulation and encapsulation technologies.  
Raw materials for formulations.  
Enzymatic hydrolysis and crosslinking of proteins for improvement of techno-functional properties

**Professional Organizations**

Gesellschaft Deutscher Chemiker